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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/783,897

02/20/2004

John T. Santini JR.

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08/24/2007

SUTHERLAND ASBILL & BRENNAN LLP

999 PEACHTREE STREET, N.E.

ATLANTA, GA 30309

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	Application No. 10/783,897	Applicant(s) SANTINI ET AL.	
	Examiner Quynh-Nhu H. Vu	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 55-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :01/19/05, 05/16/05, 08/05/05, 10/03/05, 06/12/06, 04/04/07.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed 04/04/07 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58 and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant does not disclose how/what make two reservoirs formed a single reservoir. According to Fig. 9c, it shows that there is only one/single reservoir. However, applicant denotes two reservoirs with two portions in one/single reservoir.

For examining purpose, Examiner is considering that any single reservoir can be read on claim 58.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 77 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant recites the word "microfabricated reservoirs" is too vague. The Applicant should explain clearly more details about the word "microfabricated".

For examining purpose, Examiner is considering "microfabricated reservoirs" word is same as any kind of reservoir.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 77-102 are rejected under 35 U.S.C. 102(b) as being anticipated by Currie et al. (US 5,366,454).

Regarding claims 77, 91 and 97-98, Currie discloses, Fig. 1-8, a medical device comprising: a substrate 12 or 22; a reservoir 16, it is noted that there is only one reservoir show in Figs. 1-6 and 8, however, there are plurality of compartment (reservoir) in the medical device (see abstract); reservoir provided in spaced positions across at least one surface of the substrate; reservoir caps (24 or 62, 64, 66, 68) covering the reservoir; and control circuitry for selectively disintegrating the reservoir caps to open the reservoirs (see abstract). Currie uses rupture method for reservoir caps to open the reservoirs for fluids entering into the compartment/reservoir; and upon application of an electric potential generated by the control circuitry (Fig. 6).

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Regarding claims 78-80, the molecules comprise molecules useful in medical diagnostics.

Regarding claims 81-83, 92-93, the substrate comprises silicon; two or more layers bonded together.

Regarding claims 84, 86-88 and 95-96, comprising a biosensor; power source.

Regarding claims 85 and 94, the reservoir cap comprises a metal film (62-68).

Regarding claims 89 and 102, the device adapted for implantation into a patient.

Regarding claim 98, the control circuitry comprises a cathode and a power source, wherein at least one reservoir cap 24 or 24' is an anode, and wherein application of an electric potential between the cathode and anode causes at least one of the reservoir caps to disintegrate.

Regarding claims 90 and 99-101, the reservoir comprises drug molecules.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55-76, 85 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al. (US 5,366,454).

Currie discloses, Figs. 8, an implantable device comprising: a substrate 12, 22; at least two reservoirs 16 in the substrate. It shows only one reservoir, however, it is noted that there are plurality of reservoir in the medical device (see abstract or col. 5, lines 37-40); the release system disposed in the reservoir, the release system comprising drug molecules for release; a

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reservoir cap 24 positioned over the reservoir; wherein release of the drug molecules from the device is activated by disintegration of the reservoir cap and the disintegration of the reservoir, cap is actively controlled. The membrane to be ruptured and allowing body fluids to enter into the compartment (reservoir) for mixing with the medicine contained therein so that the medicine is released in admixture with the body fluids through the delivery opening into the body fluids through the delivery opening into the human body (see abstract, lines 17-27).

Currie discloses the reservoir cap (membrane 24 or 24') formed of silicon material. The silicon membrane 24 is anodically bonded to the silicon body 12 (col. 5, lines 37-58). In other words, silicon membrane can be used as anode material. Currie does not disclose the reservoir cap formed of metal. Applicant discloses his metal reservoir cap is formed of conductive material and serves as an anode (page 21, lines 24-25 or page 33, lines 30-31). Therefore, it would have been obvious to one ordinary skill in the art substitute of one known material (such as silicon for metal) for another, since it would have yielded predictable result to one ordinary skill in the art at the time of the invention.

Additionally, Auburn (US 3,894,457) and Sapru et al. (US 4,623,597) are evidence showed that silicon (Si) and metal can be served as anode material in electrochemical.

Regarding claim 56, the substrate is comprised of two or more substrate (12 and 22) portion bonded together

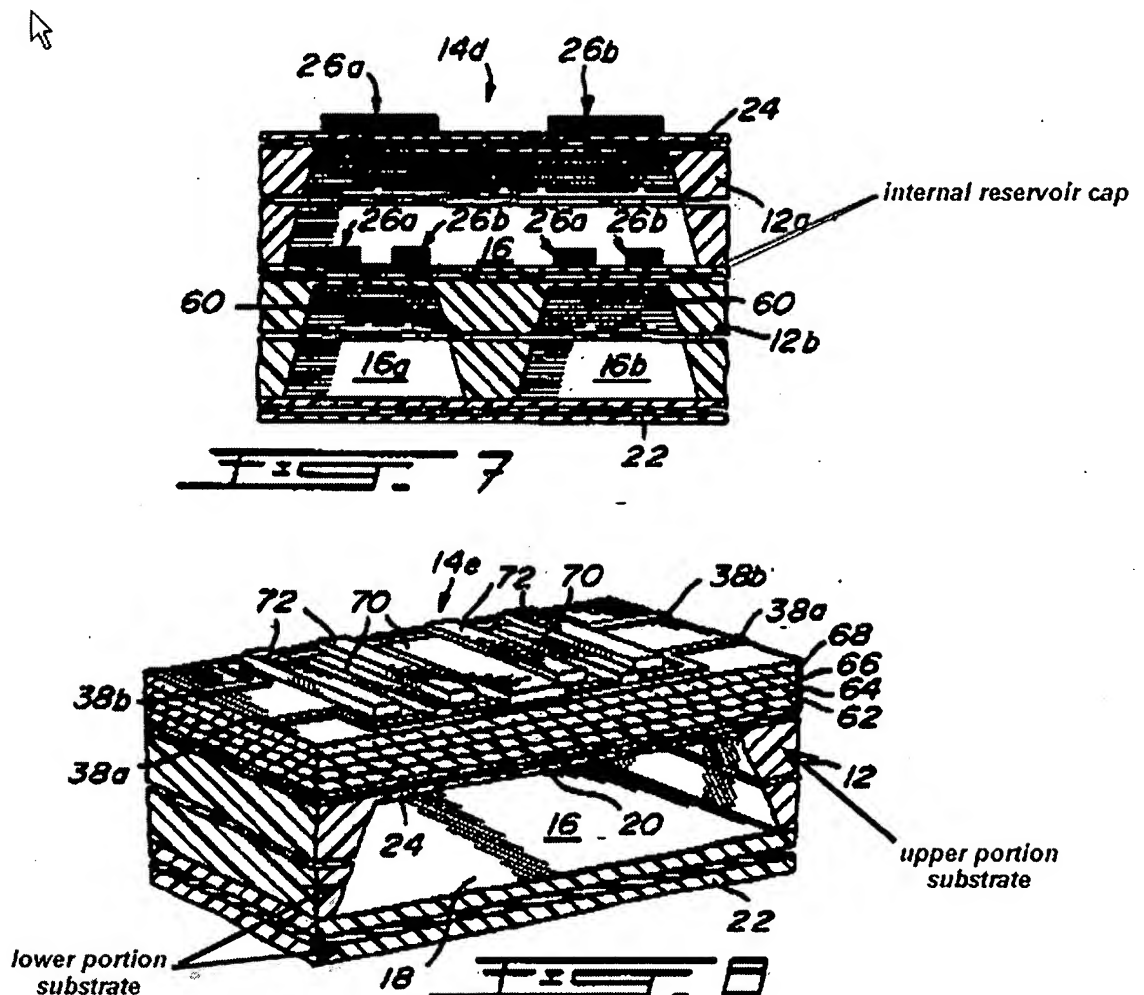
Regarding claim 57, the substrate comprises an upper substrate portion adjacent the reservoir cap and a lower substrate portion distal the reservoir cap (see Fig. 8 below).

Regarding claim 58, as best as understood, wherein a reservoir section in the upper substrate portion is in communication with a reservoir section in the lower substrate portion and the two reservoir sections forming a single reservoir (see Fig. 8 below).

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Regarding claim 57, the reservoir section in the lower substrate has a volume that is greater than the volume of the reservoir section in the upper substrate portion.

Regarding claims 57 and 61-62, as best as understood, (Fig. 7 below), the substrate comprises an upper substrate portion 12a adjacent the reservoir cap and a lower substrate portion 12b distal the reservoir cap; wherein the lower substrate portion is provided with an internal reservoir cap interposed between a reservoir section of the upper substrate portion and a reservoir section of the lower substrate portion, wherein release of the molecules from the reservoir section in the lower substrate portion is controlled by diffusion through or disintegration of the internal reservoir cap.





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Regarding claims 63-64, the disintegration of the reservoir cap is activated by application of electrical energy through the reservoir cap (see abstract, and Fig. 6).

Regarding claims 65-67, Currie discloses the claimed invention except for the release system comprises matrix material or biodegradable or bioerodible polymeric material; and the drug molecules comprises anesthetics, vaccines, chemotherapeutic, etc.... It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the materials mentioned above, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claim 68, the disintegration of the reservoir caps is controlled by a preprogrammed microprocessor.

Regarding claims 69-76, similar to rejection of claims 55-68 above. Furthermore, Currie discloses that the device is activated by disintegration of the reservoir cap by direct application of an electrical potential through the reservoir cap (see abstract, or col. 2, lines 47-65).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 55-56, 64-65, 67 and 69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7-8 and 19-20 of U.S. Patent No. 5,797,898. Although the conflicting claims are not identical, they are not patentably distinct from each other because an implantable medical device of instant claim is fully disclosed and covered by the U.S. Patent No. 5,797,898.

Claims 77-78, 81, 83, 85, 89-91, 93-94 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-7, 10-12, 15-16 of U.S. Patent No. 7,070,592. Although the conflicting claims are not identical, they are not patentably distinct from each other because an implantable medical device of instant claim is fully disclosed and covered by the U.S. Patent No. 7,070,592.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QNV



LOAN H. THANH  
PRIMARY EXAMINER